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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,681	02/01/2001	Linda A. Sherman	313332000101	3045

21874 7590 03/11/2003

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EXAMINER
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DECLoux, AMY M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 03/11/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n N .

09/774,681

Applicant(s)

SHERMAN ET AL.

Examiner

Amy M. DeCloux

Art Unit

1644

-- The MAILING DATE of this c mmunication appears on the c ver sheet with the c rrespondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 6-31 is/are pending in the application.
- 4a) Of the above claim(s) 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 6-19 and 22-31 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Pri rity under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Applicant's amendment filed 12-26-02, (Paper No. 14) is acknowledged and has been entered. However, in view of newly added claims 22-31, a species requirement has been imposed.

#### *Election/Restrictions*

This application contains claims directed to the following patentably distinct species of the claimed invention: An isolated nucleic molecule which comprises a nucleotide sequence encoding a variable region of a nonhuman TCR  $\alpha$  or  $\beta$  peptide, wherein said peptide is an alpha or beta peptide as recited in claim 6 or a single chain TCR as recited in claim 10, wherein said peptide is from a species such as murine as recited in claim 9, wherein said TCR is human HLA-restricted for an HLA such as an HLA recited in claim 23, and wherein said TCR is specific for a tumor-associated antigen such as an antigen recited in claim 22, wherein the variable region of the non-human TCR  $\alpha$  or  $\beta$  peptide is directly coupled to a transmembrane and cytoplasmic region of a receptor of a species, such as the zeta region of human CD3, wherein said region consists of a sequence such as that recited in claim 24, wherein said single chain TCR peptide comprises a flexible linker, such as one recited in claim 12, and a hinge such as that recited in claim 26.

Accordingly, Applicant is required to elect an isolated nucleic molecule which comprises a nucleotide sequence encoding a variable region of a nonhuman TCR  $\alpha$  or  $\beta$  peptide, wherein said peptide is a **specific peptide** such as either alpha or beta peptide as recited in claim 6 or a **specific single chain TCR** as recited in claim 10, wherein said peptide is from a **specific species** such as murine as recited in claim 9, wherein said TCR peptide is human HLA-restricted for a **specific HLA** such as an HLA recited in claim 23, wherein said TCR is specific for a **specific tumor-associated antigen** such as an antigen recited in claim 22, wherein the variable region of the non-human TCR peptide is directly coupled to a **specific transmembrane and cytoplasmic region** of a **specific receptor** of a **specific species**, such as the zeta region of human CD3, wherein said region consists of a **specific sequence** such as that recited in claim 24, wherein said single chain TCR peptide comprises a **specific flexible linker**, such as one recited in claim 12, and a **specific hinge** such as that recited in claim 26.

Said species are distinct because each has a distinct structure which confers unique functional properties.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 6-31 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 872-9306 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux  
Patent Examiner  
Group 1640

March 1, 2003

*Amy DeCloux*

3-1-03